

JAN 08 2003

K023481

**510(k) Summary**

**for**

**MicroVision Scleral Buckling Components**

**1. SPONSOR**

MicroVision, Inc.  
34 Folly Mill Road, Suite 200  
P.O. Box 1651  
Seabrook, NH 03874

Contact Person: Leonard Kastrilevich  
Telephone: 603-474-5566

Date Prepared: October 16, 2002

**2. DEVICE NAME**

Proprietary Name: MicroVision Scleral Buckling Components  
Common/Usual Name: Scleral Buckling Components  
Classification Name: Nonresorbable Extraocular Orbital Implants

**3. PREDICATE DEVICES**

MicroVision, Inc. claims substantial equivalence to the solid silicone and silicone sponge implants cleared for marketing under the following 510(k)s:

- Mira, Inc. (K950806)
- Storz Ophthalmics, Inc. (K832481, K950599)
- Labtician Ophthalmics, Inc. (K875014)

**4. INTENDED USE**

The MicroVision Scleral Buckling Components are solid silicone and silicone sponge implants intended for intrascleral and episcleral buckling in the surgical treatment of retinal detachments.

**5. DEVICE DESCRIPTION**

The MicroVision Scleral Buckling Components are molded solid silicone and silicone sponge devices available in a variety of shapes and sizes. The components

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are provided as sterile for single use only. Biocompatibility testing conducted according to ISO 10993 confirmed that the components are biocompatible and non-toxic.

#### **6. BASIS FOR SUBSTANTIAL EQUIVALENCE**

The MicroVision Scleral Buckling Components have the same intended use as the listed predicate products, that is, for scleral buckling in retinal reattachment surgery. All of the products are made of molded silicone, either in solid or sponge form, are provided sterile for single use only, and are available in a wide variety of shapes and sizes. All products have been demonstrated to be biocompatible and non-toxic. Bench testing was conducted to demonstrate that the MicroVision products are substantially equivalent to the predicates with respect to dimensional and physical properties.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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MicroVision, Inc.  
Sheila Hemeon-Heyer, JD, RAC  
c/o Medical Device Consultants, Inc. (MDCI)  
49 Plain Street  
North Attleboro, MA 02760

Re: K023481

Trade Name: MicroVision Scleral Buckling Components  
Classification Regulation Number: 886.3340  
Regulatory Class: II  
Product Code: HQX  
Dated: October 16, 2002  
Received: October 17, 2002

Dear Dr. Hemeon-Heyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

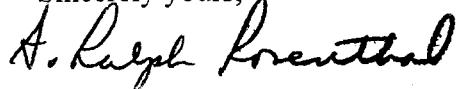
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



A. Ralph Rosenthal, M.D.  
Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

510(k) Number (if known): K 023481

Device Name: MicroVision Scleral Buckling Components

Indications for Use:

The MicroVision Scleral Buckling Components are solid silicone and silicone sponge implants intended for intrascleral and episcleral buckling in the surgical treatment of retinal detachment.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Dusanna J. Jones  
(Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices

510(k) Number K 023481

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)